

From: [Ogulei, David](#)
To: [Damico, Genevieve](#); [Marcus, Danny](#)
Subject: RE: news
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FYI, there wasn't much discussed during the Medline call this morning. Medline is still considering multiple options for their emission reduction project. They expect to make a decision on the specific scope of the project by early to mid-January.

From: Damico, Genevieve
Sent: Thursday, December 20, 2018 2:22 PM
To: Ogulei, David <Ogulei.David@epa.gov>; Marcus, Danny <marcus.danny@epa.gov>
Subject: news

Officials knew ethylene oxide was linked to cancer for decades. Here's why it's still being emitted in Willowbrook and Waukegan.



Breast cancer survivor Julie Cannell at her Riverside home on Dec. 19, 2018. Cannell grew up near Sterigenics in Willowbrook. (Antonio Perez/Chicago Tribune)

[Michael HawthorneContact Reporter](#)Chicago Tribune

When Julie Cannell was born in the 1980s, the Sterigenics plant in Willowbrook churned up to 169,000 pounds of cancer-causing ethylene oxide into the air every year.

Cannell grew up about a mile from the facility in a leafy suburban

neighborhood of big homes and even bigger yards. She attended public schools close to Sterigenics. But like most residents of the DuPage County village, she had no idea the company existed until this summer, when the [U.S. Environmental Protection Agency](#) singled out Willowbrook as one of a few dozen communities across the nation facing alarmingly high cancer risks from toxic air pollution.

Diagnosed with breast cancer in 2014, shortly after her 30th birthday, Cannell endured a double mastectomy and rounds of debilitating radiation and chemotherapy. Now she is among dozens of cancer survivors and families of victims wondering if daily exposure to an obscure industrial chemical contributed to the diseases.

“My parents moved to Willowbrook because my dad felt like we were living in the country, with fresh air and plenty of open spaces,” Cannell said. “This wasn’t supposed to happen.”

While it is difficult, if not impossible, to determine why cancerous cells suddenly develop in people, scientists have been reporting for decades that toxic chemicals are among the triggers. “The true burden of environmentally induced cancer has been grossly underestimated,” a [presidential commission of experts concluded in 2010](#).

“The public remains unaware of many common environmental carcinogens,” the [President’s Cancer Panel](#) said in its report, listing ethylene oxide as one of the examples. “Most also are unaware that children are far more vulnerable ... than adults.”

Chemical companies and government health agencies [have known since at least the late 1970s](#) that ethylene oxide mutates genes and causes breast cancer, leukemia and lymphomas. After owners of the Willowbrook plant applied for a new permit in the mid-1980s, state regulators estimated that people living within a mile of the facility could end up breathing the highly toxic gas [at concentrations 14 times higher than studies suggested was safe at the time](#).

Yet time and time again, a Chicago Tribune investigation found, the [multibillion-dollar chemical industry](#) and its [political allies in Washington](#) have thwarted, weakened or delayed efforts to limit exposure to ethylene oxide, relying on the same tactics used to stall action on more well-known hazards like lead and asbestos.

Sterigenics, which uses ethylene oxide to sterilize medical equipment, pharmaceutical drugs and food in Willowbrook and eight other U.S. locations, has played a [key role in the chemical industry's defense](#).

As a result, the public health impacts are only now becoming clear.

Timeline: The history of ethylene oxide, from WWII food rations to suburban air pollution

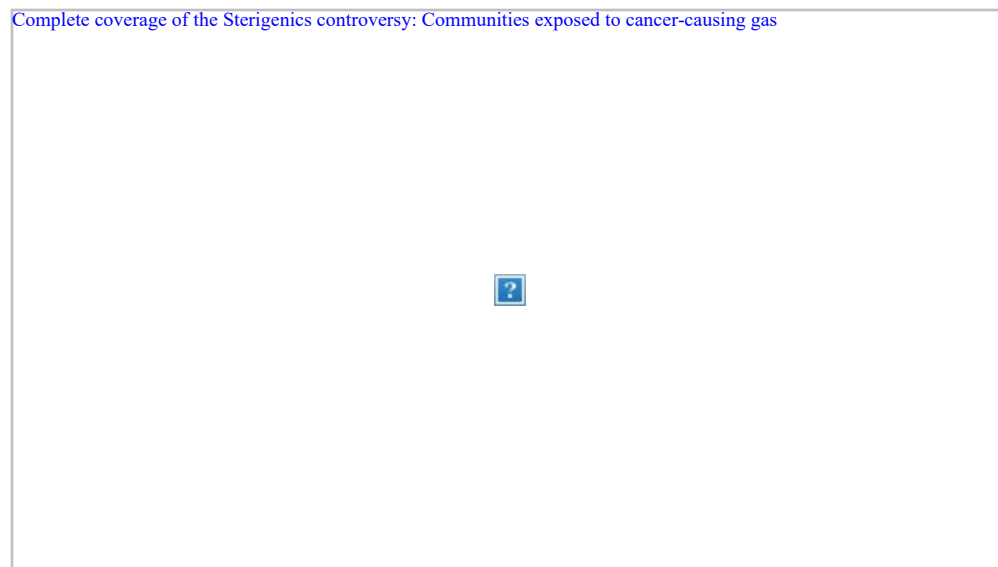


More than 600,000 Americans face what the EPA considers unacceptable long-term cancer risks from breathing toxic air pollution, according to a Tribune analysis of data quietly released in [August by the agency](#). Ethylene oxide is the chief chemical responsible in nearly all of those communities, including neighborhoods near [Sterigenics in Willowbrook](#) and [Medline Industries in north suburban Waukegan](#).

The chemical and sterilization industries, along with Medline and other manufacturers of medical products, contend ethylene oxide is essential to prevent potentially deadly infections during surgery and other procedures.

There is no doubt the chemical is effective at killing bacteria and pests. But safer sterilization methods are available, industry records show, raising questions about whether efforts to preserve the use of ethylene oxide are motivated by financial interests rather than a desire to protect public health.

Citing Tribune reporting about ethylene oxide during the past four months, federal and state elected officials are calling for more aggressive measures to protect the public.



U.S. Sens. Dick Durbin and Tammy Duckworth, and U.S. Reps. Bill Foster, Dan Lipinski and Brad Schneider have introduced legislation that would require the EPA to adopt tougher regulations for Sterigenics and other sterilization companies. Illinois Attorney General Lisa Madigan and Robert Berlin, the DuPage County state's attorney, have sued to [shut down the Willowbrook facility as a public nuisance](#). Two DuPage Republicans in the state legislature, Sen. John Curran and House Minority Leader Jim Durkin, have introduced bills that would force the sterilization industry to phase out the use of ethylene oxide in Illinois.

There even are signs President Donald Trump's administration might detour from its anti-regulatory agenda to address the cancer risks. William Wehrum, whom Trump appointed to head the federal EPA's air office, recently told the crowd at a Willowbrook public forum that the agency is considering more stringent national limits on the chemical.

Chemical companies and [sterilization firms](#) are pushing back, citing industry-funded studies rejected by the EPA and two panels of independent scientists that reviewed the agency's updated assessment of ethylene oxide risks.

[New EPA tests near Sterigenics show ethylene oxide cancer risks haven't disappeared](#)



Conclusions in the [agency's report](#), published in December 2016, remained largely unchanged from a [2006 draft](#) based on decades of animal research and a large federal study of sterilization workers. But the American Chemistry Council, the industry's chief trade group, is [petitioning the Trump administration to take another look](#).

“The science hasn’t changed,” said Peter Thorne, a [University of Iowa toxicologist](#) who [led one of the review panels](#). “What's changed is the agency and the political winds in Washington. This is another opportunity for (industry) to get its way.”

At least one person at the highest levels of the Trump EPA is on the side of chemical manufacturers: Nancy B. Beck, who was an [executive at the industry trade group](#) before her April 2017 appointment as a [top deputy in the EPA's chemical safety unit](#).

Less than a month before Beck got her job in the new Republican administration, she testified before a Senate committee in favor of [GOP-](#)

[sponsored proposals that would dramatically overhaul the way the EPA evaluates risks to public health and wildlife.](#) The measures, which have been sought by industry for decades, would effectively make it more difficult to restrict hazardous chemicals.

By formally concluding that regular exposure to less than 1 part per trillion of ethylene oxide is dangerous, Beck told the committee, the EPA “will needlessly cause alarm and confusion, not only among workers, but also in the general population and in the public health and medical communities.” The agency’s risk assessment is “not plausible, and not scientifically supportable,” she said.

The EPA declined to answer detailed questions about Beck, including whether she should recuse herself from internal agency debates about chemicals she lobbied for on behalf of industry.

“Dr. Beck has not been involved” in the agency’s current efforts regarding ethylene oxide, said John Konkus, an EPA spokesman.

[New documents reveal how Sterigenics, other companies were allowed to vent cancer-causing gas into communities](#)



Thorne and others who reviewed the science said industry has failed to provide new evidence that would undermine the agency’s review.

“It’s been through two rounds of public comment. It’s been through two rounds of peer review,” said David Bussard, director of the Washington

office of the National Center for Environmental Assessment, an arm of the EPA that prepared the 2016 report. “We stand behind it.”

The vast majority of ethylene oxide produced worldwide is used to manufacture other chemicals, in particular ethylene glycol, a key ingredient in antifreeze, polyester fabrics and plastics. Major producers include Dow Chemical, Shell, Huntsman and Union Carbide (now a subsidiary of Dow).

Industry scientists realized during the 1920s that the gas also kills insects and other pests. One of the first companies to take advantage of its potency was Griffith Laboratories, a supplier to Chicago meatpackers that [patented methods](#) using ethylene oxide pumped into sealed chambers to fumigate spices and other food preservatives.

Griffith’s researchers discovered that ethylene oxide kills bacteria without altering metal, wood or plastic, drawing interest from hospitals, medical suppliers and the U.S. Army’s biological weapons program. The company expanded its operations to include surgical devices and later spun off its sterilizers into another firm called Griffith Micro Science, which became Sterigenics after a corporate takeover during the late 1990s.

Competitors developed other methods that over the years have reduced the reliance on ethylene oxide. Half of all medical instruments and devices produced in the United States during the late 1980s were sterilized with gamma rays or electron beams, killing bacteria and viruses without lingering dangers from the radiation, [according to an EPA survey](#). Other companies determined that chemicals safer than ethylene oxide were effective germ-killers, including hydrogen peroxide and peracetic acid.

What is ethylene oxide, the cancer-causing chemical used by Sterigenics and other Chicago-area companies?

But every time federal or state regulators attempt to protect Americans from ethylene oxide, industry groups stoke the public's fear of hospital infections.

“Any disruption to the operations of the Sterigenics Willowbrook facility would seriously undermine the ability to proceed with scheduled surgeries and procedures and would put patients' lives at risk,” the company [said in an October statement](#), echoing what [industry executives](#) have been [telling lawmakers and the EPA for decades](#).

“There is no doubt that EO has prevented millions of deaths related to infection,” Mark Biel, the [chemical industry's chief Illinois lobbyist](#), told state lawmakers at an October hearing, using one of the abbreviations of ethylene oxide. “If an EO sterilization facility shuts down, there is no place else to go.”

More nuanced views are outlined in a 2017 report from the [Association for the Advancement of Medical Instrumentation](#), a trade group that counts Sterigenics and Medline as members. Charts compiled by the group's standards board show virtually every type of material in medical products can be sterilized without ethylene oxide. The report noted that companies might not switch to alternatives because they “have significant investment in one particular sterilization method.”

The first study detailing how ethylene oxide causes genetic mutations was

published in 1948. During the 1970s, animal studies confirmed that its powerful ability to scramble DNA could trigger cancers, prompting attention from the EPA and the Occupational Safety and Health Administration, both of which at the time were relatively new federal agencies created to address industrial hazards.

“Every study we looked at showed this is a very dangerous chemical,” said Peter Infante, an epidemiologist who at the time directed OSHA’s Office of Carcinogen Identification. “The evidence was clear that we needed to act quickly to protect workers.”

Industry insiders appeared to agree. In August 1981, a top executive at Shell returned from a scientific conference and reported the closing speaker had said “the biggest problem chemical that we have right now is ethylene oxide,” according to a [memo the Tribune found](#) in a [trove of industry documents](#) made public during lawsuits against chemical makers.

Days before the Shell executive alerted his peers, the nonprofit group Public Citizen and the American Federation of State, County and Municipal Employees union had petitioned OSHA for emergency standards that would dramatically lower workplace exposures to 1 part per million from 50 ppm averaged over eight hours, and limited short-term bursts to 5 ppm.

[Trump and Rauner administrations knew about Sterigenics cancer risks months before telling public](#)



Instead of acknowledging the well-documented hazards, the chemical

industry chose to fight, enlisting the influential American Hospital Association and the Veterans Administration in its lobbying campaign, according to minutes from a November 1981 [meeting of the trade group's board of directors](#).

Chemical makers found a sympathetic audience in a new presidential administration. Like Trump in 2016, Ronald Reagan had campaigned in 1980 “to get the government off people’s backs.” Once in office, Reagan’s staff dispatched Republican operatives to rein in federal regulatory agencies and directed the White House budget office to block or delay new environment and safety rules.

The Reagan-controlled OSHA denied the ethylene oxide petition, [then spent the next seven years fighting it in the courts](#), backing down only after a federal appellate court sharply condemned the agency’s “hesitation and lack of resolve.”

“They were shilling for industry,” said David Vladeck, a [Georgetown University law professor](#) who sued OSHA for the tougher ethylene oxide standards while working for Public Citizen. “Imagine how many workers were harmed because these guys were just playing power games behind the scenes to delay the regulations.”

It has taken even longer to address the health risks to Americans outside the workplace.

When Griffith applied for a permit in 1984 to build six sterilizers at its Willowbrook facility, the [Illinois Environmental Protection Agency](#) urged the company to take steps to reduce the amount of ethylene oxide it released into surrounding communities. But the state agency noted it didn’t have legal authority at the time to order improvements.

The federal EPA didn’t require the sterilization industry to install pollution-control equipment until the late 1990s, then [relaxed the regulations a few years later](#) in response to explosions at plants in Indiana, Massachusetts,

Virginia and Wisconsin. Griffith helped persuade regulators [the government-mandated pollution controls were responsible for the blasts](#), though investigators found operator errors were to blame in each case and could have been prevented with more rigorous training and safer handling of the highly volatile chemical.

[2 Lake County polluters emit same cancer-causing gas as Sterigenics, but authorities haven't warned the public](#)



In 2006, the EPA decided it would [formally join other agencies](#) that already had declared the chemical causes cancer in humans, including the [World Health Organization](#), the [National Toxicology Program](#) and the [state of California](#).

EPA scientists relied on animal research and a study of more than 18,000 workers at 17 sterilization plants conducted by the National Institute of Occupational Safety and Health. They adjusted their proposed safety limit to account for people in the general population who are particularly sensitive to chemical exposures. For the first time, the EPA applied additional safety factors to protect children, who are more susceptible to cancer-causing chemicals.

Re-evaluating toxic substances often leads to conclusions that they are more hazardous than scientists once thought. The EPA and Centers for Disease Control and Prevention say there is no safe level of exposure to brain-damaging lead, for instance, though in 1990 the agencies still thought children weren't harmed until concentrations in their blood exceeded 30

parts per billion.

The EPA's draft report about ethylene oxide should have been the first step toward more stringent regulations. Instead, it prompted another decade of delay.

Industry agreed the NIOSH study of sterilization workers was well-done. But representatives for chemical manufacturers and sterilization companies urged the EPA to merge the results with another worker study funded by Union Carbide — one of the corporations that makes ethylene oxide.

Muddying the science is a tactic that has worked wonders for industry over the years, starting with corporations that denied people could be harmed by [lead in gasoline, paint and water](#). Big Tobacco [financed its own research](#) to disguise the risks of smoking, and some of its executives later helped pioneer the use of industry-funded studies to raise doubts about the dangers of pesticides, industrial chemicals and [flame retardants](#).

Few of those studies held up to close scrutiny. Neither did the Union Carbide study of ethylene oxide workers, according to the EPA and the agency's scientific advisers.

“There were a whole host of reasons why that study was weak,” said Thorne, the University of Iowa toxicologist who reviewed studies of ethylene oxide while leading the [EPA's Science Advisory Board](#). “Too few cases, mixed exposure to carcinogens other than ethylene oxide, few or no women, very few actual measurements of exposure. As near as I can tell, the American Chemistry Council wanted us to use it because it would produce an ambiguous or negative outcome.”

Industry has continued to cite the Union Carbide study, just as it has done with misleading research about other hazardous substances.

Few people noticed outside the EPA and the executive suites of chemical companies when the agency released the final version of its risk assessment in late 2016, a few weeks before the Trump administration took office.

The main reason it's being debated again is the EPA relied on its latest evaluation of ethylene oxide while compiling new estimates of cancer risks from toxic air pollution in every community in the United States.

Out of 73,057 census tracts in the nation, the EPA's [National Air Toxics Assessment](#) identified 109 where the risks exceed agency guidelines. Seven surround Sterigenics in Willowbrook; another four are near Medline in Waukegan. In response to Tribune reporting, the agency announced in November that it also is taking a closer look at [Vantage Specialty Chemicals in Gurnee](#), which reported emitting more ethylene oxide than Sterigenics or Medline but because of a clerical error wasn't included in the EPA's initial analysis.

Medline responded by hiring Jane Teta, the [former director of epidemiology at Union Carbide](#) and an author of the industry studies rejected by the EPA. Teta, who has worked as a consultant for the American Chemistry Council, is now a scientist at [Exponent](#), a California-based firm with a [long history of questioning the health risks of widely used chemicals](#).

Teta [told legislative committees in Springfield last month](#) that if anything is flawed, it is the EPA's assessment of ethylene oxide. "It's an abuse of science," she testified, urging lawmakers to ignore the agency's estimates of cancer risks in Willowbrook and Waukegan.

Industry representatives also contend the chemical is naturally produced in the body at levels 19,000 times greater than the EPA's new safety limit. Asked for evidence to back up their claims, they cite a [2017 industry-funded study in a journal edited by a former consultant for Big Tobacco who frequently publishes findings that end up in the chemical industry's lobbying materials](#).

Richard Peltier, an environmental health researcher at the University of Massachusetts Amherst, reviewed the study for Lipinski's office. The methodology used by the industry-funded researchers appears to have been

designed to produce the results they wanted, Peltier said, noting they ignored research on low-level exposures to animals and based their analysis largely on industrial workers who generally are healthier than the general population.

“They just made stuff up,” Peltier said in an interview. “It’s another attempt to throw mud on the wall to see if it will stick.”

Residents and elected officials in Willowbrook aren’t buying the industry’s arguments, either.

At her home less than 500 yards from Sterigenics, Sue Kamuda recalls shaking uncontrollably when she first learned about the company’s pollution in August. The fear, sadness and anger she felt when doctors told her she had breast cancer in 2007 came flooding back, tempered only by reminding herself she survived and lived long enough to retire comfortably and see her eight grandchildren grow up.

Kamuda got angry again when she heard Biel, the chemical industry lobbyist, tell state lawmakers that plastic water bottles wouldn’t exist without ethylene oxide. And when she listened to a Sterigenics representative tell a community forum that some medical devices can’t be sterilized without the chemical.

“They’ve been poisoning us for years and they knew it,” said Kamuda, who moved to Willowbrook in 1985. “The only solution is for them to get out of town. Now.”

Cannell, the breast cancer survivor who grew up in Willowbrook, initially brushed off fears about the lump she felt in one of her breasts while getting dressed for her 30th birthday party. “It’s still fairly rare for women my age to get breast cancer,” she recalled thinking.

“A lot of things had been moving forward in my life at that point,” said Cannell, who now lives in Riverside and is married with a young daughter. “It’s taken a long time to get my life back on track, and I can’t help but think

that company is somehow responsible. We need to make sure this doesn't happen again somewhere else."

mhawthorne@chicagotribune.com